Translation

PCT/FR2003/001096

PATENT COOPERATION TREATY

PCT Rec'd PCT/PTO 06 OCT 2004

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FLAMEL 0077	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/FR2003/001096	International filing date (*day/month/year*) 07 avril 2003 (07.04.2003)	Priority date (*day/month/year*) 09 avril 2002 (09.04.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/50		
Applicant FLAMEL TECHNOLOGIES		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 27 octobre 2003 (27.10.2003)	Date of completion of this report 21 July 2004 (21.07.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

Form PCT/IPEA/409 (cover sheet) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR2003/001096

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☒ the description:
pages 1-22, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:
pages 1-20, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the drawings:
pages 1/2-2/2, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR 03/01096

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following documents:

D1: EP-A-624 371
D2: WO 96 11 675 A

Except where otherwise indicated, reference is made to the passages of D1 cited in the search report. D2 is cited by the examiner. A copy is attached to the present written opinion.

Novelty

D1 describes acetylsalicylic acid microcapsules with a coating layer. Said microcapsules can be administered in the form of a suspension (example 4). The fact that the active ingredient is released by diffusion in the suspension medium is not mentioned. D2 describes coated microcapsules as defined in claim 1 (D2, page 9, line 4 to page 10, line 12), and the use thereof for preparing controlled-release systems having a plurality of classes of active ingredients (page 4, line 27 to page 15, line 10). Therefore, the subject matter of claims 1-20 appears to be novel over D1 and D2 (PCT Article 33(1) and (2)).

Even if a specific active ingredient could be selected,

the subject matter of said claims are not considered to be inventive. D1 is the closest prior art. The present application differs therefrom by virtue of the fact that the microcapsules are formulated as a suspension. From the example given in D2, or the general therapeutic principle that a suspension is advantageous as compared, for example, with capsules or tablets in the case of patients who find it difficult to swallow (paediatric or geriatric patients), a person skilled in the art would arrive at the solution provided in the present application. The solvent phase would be saturated by the diffusion of the active ingredient from the microcapsules.

The prior art documents cited do not mention adding the free active ingredient to the suspension medium (claim 8). Nevertheless, this would be envisaged by a person skilled in the art seeking to provide for the immediate availability of at least a portion of the active ingredient.

For these reasons, the subject matter of claims 1-20 is not considered to be inventive (a13).

The active ingredient release profiles (claims 11 and 12) and the diffusion percentage of the active ingredients in the microcapsules (claim 5) are not mentioned in the prior art, but they appear to be a result that is sought rather than a precise definition of the invention. Therefore, said claims do not meet the requirements of PCT Article 6.